

**DETAILED ACTION**

***Election/Restrictions***

1. Applicant's election with traverse of Group I, claims 1 and 74-81 in the reply filed on 02/06/09 is acknowledged. Examiner notes independent claim 82 is drawn to a labeling station, restricted to Group II, claims 82-83. Applicant elected the group drawn to the automated pharmaceutical dispensing system which does not include independent claim 82 (see interview summary). The traversal is on the ground(s) that Sleep does not disclose a single labeling station. This is not found persuasive because Applicant has not identified a common special technical feature between the restricted groups. Examiner notes not all claimed groups include a label applicator means which alters the way a label is applied. Furthermore, the current claim language does not exclude additional labelers. The term "means for applying the label" may include multiple, separate labelers as taught by Sleep. Additionally, an apparatus exclusively comprising a single labeler to apply labels of various orientations is known in the art as shown by Jenkins, and therefore cannot be a common special technical feature. Consequently, this argument is not persuasive.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 82-128 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 02/06/09.

***Information Disclosure Statement***

3. The information disclosure statement filed 09/06/06 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information referred to therein has not been considered.

***Claim Objections***

4. Claim 81 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. It is unclear how dependent claim 81 further limits independent claim 81. Examiner notes independent claim 1 is drawn to an apparatus and does not positively recite a label or a pack. Inclusion of material or article worked upon by a structure being claimed does not impart patentability to the claims. In re Young, 75 F.2d 966, 25 USPQ 69 (CCPA 1935) (as restated in In re Otto, 312 F.2d 937, 136 USPQ 458, 459 (CCPA 1963)). Therefore, the label size and pack size do not provide any structural limitations to the currently claimed apparatus.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1 and 74-81 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Independent claim 1 requires the means for applying a label is adapted to alter the way in which the label is applied depending upon the dimensions of the pack to be labeled. The specification does not adequately describe an applicator which alters "the way" a label is applied. On the contrary, the specification appears to disclose an applicator which applies labels in the same manner on different sized packs (See Figures 5-6). The breadth of the claims is sufficiently broad such that it is unclear how the required function would be performed. The nature of the invention does not appear to indicate a change in "the way" a label is applied. The inventor has not provided any direction as to how one alters the way a label is applied. No working examples have been provided which demonstrate various ways of applying labels. Clarification is required. Claims 74-81 are rejected due to dependency on independent claim 1.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1 and 74-81 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Independent claim 1 requires the means for applying a label is adapted to alter the way in which the label is applied depending upon the dimensions of the pack to be labeled. It is unclear how a labeler alters "the way" a label is applied. On the contrary, the specification appears to disclose an applicator which applies labels in the same manner on different sized packs (See Figures 5-6). While it appears some variation in orientation may be employed (Figure 7), such an alteration does not constitute a change in "the way" the label is applied or the structure of the apparatus. Furthermore, the packs are not positively recited as features of the currently claimed apparatus. It is unclear how the apparatus structure may be dependent upon its contents. Clarification is required. Claims 74-81 are rejected due to dependency on independent claim 1.

9. As to claim 75, it is unclear what is meant by "appropriately". Would it be appropriate to arrange the pack and label applicator in any orientation? It is unclear what structural limitations are imparted by this language.

10. With respect to claim 76, the phrase, "is arranged to adjust its orientation" is unclear. It is unclear how the arrangement of the applicator adjusts its orientation. It is unclear what structural feature is being recited. The term "to adjust" suggests an intended use and does not structurally contribute to the current apparatus claims.

11. As to claim 77, it is unclear how a station is "adapted to receive an instruction". What structural feature is being recited? It is unclear what "instruction" is received. It is also unclear what structure of the labeling station receives instruction.
12. As to claim 79, it is unclear how a system may be "arranged to pass information to the labeling system to enable the label applicator to apply the label in the predetermined position." What structural arrangement is being claimed? Is the information a structural feature of the currently claimed apparatus? What structure passes information?
13. With respect to claim 80, it is unclear how a system is "arranged to pass label positioning information". What structural arrangement is being claimed? Is the information a structural feature of the currently claimed apparatus? What structure passes information? It is also unclear if claim 80 further limits independent claim 1. The data received and transmitted by a controller/computer is drawn to the intended use of the apparatus and does not structurally define the apparatus.
14. Claims 76 and 78-80 recite the limitation "the label applicator". There is insufficient antecedent basis for this limitation in the claim.
15. Claim 79 recites the limitation "the predetermined position". There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 102***

16. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

17. Claims 1, 74-75, and 77-81 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,317,648 to Sleep et al.

18. With respect to claim 1, the terms “means for applying the label”, “means for selecting and retrieving”, and “means for delivering” are being treated under 35 U.S.C. 112, sixth paragraph. Sleep et al. discloses a labeling apparatus, including means for selecting and retrieving (26) a pharmaceutical pack, said means being arranged to deliver said pack to a labeling station (32/38/34), wherein said labeling station comprises a label printer (34) arranged to print a label comprising information specific to a patient for whom said pharmaceutical pack is intended, and means for applying said label (i.e. different labelers; 38; column 10, lines 27-35) to said pack; the system further comprising means for delivering (i.e. output; column 10, lines 7-9) said pack from the labeling station so as to be accessible to a user, wherein the means for applying the label is adapted to alter the way in which the label is applied depending upon the dimensions of the pack to be labeled (column 10, lines 27-35).

19. Examiner notes the flex filler (26) is treated as equivalent to the “means for selecting and retrieving” and the output is equivalent to “means for delivering” recited in independent claim 1 under 35 U.S.C. 112, sixth paragraph because the disclosed

structure performs the identical function specified in the claim in substantially the same way, and produces substantially the same results as the corresponding element disclosed in the specification (i.e. robot 4). The different labelers (38) are treated as equivalent to the "means for applying the label" recited in independent claim 1 under 35 U.S.C. 112, sixth paragraph because the disclosed structure performs the identical function specified in the claim in substantially the same way, and produces substantially the same results as the corresponding element disclosed in the specification (i.e. labeler, 22).

20. Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. Ex parte Thibault, 164 USPQ 666, 667 (Bd. App. 1969). Consequently, the pharmaceutical packs and labels are not structurally limiting to the currently claimed apparatus.

21. The examiner would like to note that while features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. In re Schreiber, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997); "[A]pparatus claims cover what a device is, not what a device does." Hewlett-Packard Co. v. Bausch & Lomb Inc., 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (emphasis in original). A claim containing a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus" if the prior art apparatus teaches all the structural limitations of the claim. Ex parte Masham, 2 USPQ2d 1647 (Bd. Pat. App. &

Inter. 1987). Examiner notes the phrases "comprising information specific to a patient for whom said pharmaceutical pack is intended" and "so as to be accessible to a user" are drawn to the intended use of the currently claimed apparatus and do not further structurally define the apparatus. See MPEP § 2114.

22. As to claim 74, Sleep et al. discloses the apparatus is arranged such that the labeling station (38) applies the label in an orientation (column 10, lines 27-35) relative to the pack. The phrase, "which is dependent upon at least one dimension of the pack" is drawn to the contents of the apparatus and does not structurally contribute to the currently claimed apparatus.

23. As to claim 75, Sleep et al. discloses the labeling station is arranged to orient the pack and label applicator (38) appropriately (column 10, lines 27-35).

24. As to claim 77, Sleep et al. discloses the labeling station is adapted to receive an instruction as to how the label is to be applied (column 10, lines 27-35).

25. As to claim 78, Sleep et al. discloses the label applicator is arranged to apply the label at a predetermined position on the pack (column 10, lines 27-35). The phrase "the position being variable from one pack type to another" is drawn to the contents of the apparatus and does not structurally contribute to the currently claimed apparatus.

26. As to claim 79, Sleep et al. discloses the apparatus is arranged to pass information to the labeling station to enable the label applicator to apply the label in the predetermined position (column 10, lines 27-35).



27. As to claim 80, Sleep et al. discloses the apparatus is arranged to pass label positioning information directly to the labeling station or label applicator (column 10, lines 27-354).

28. As to claim 81, Inclusion of material or article worked upon by a structure being claimed does not impart patentability to the claims. In re Young, 75 F.2d 966, 25 USPQ 69 (CCPA 1935) (as restated in In re Otto, 312 F.2d 937, 136 USPQ 458, 459 (CCPA 1963)). Therefore, the label size and pack size do not provide any structural limitations to the currently claimed apparatus. Sleep et al. discloses the apparatus is arranged to apply a label of common size to all packs (column 10, lines 27-35).

29. Claims 1 and 72-81 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,672,356 to Jenkins et al.

30. With respect to claim 1, the terms "means for applying the label", "means for selecting and retrieving", and "means for delivering" are being treated under 35 U.S.C. 112, sixth paragraph. Jenkins et al. discloses a labeling system, including means for selecting and retrieving (10/12/20/28/30) a pack, said means being arranged to deliver said pack to a labeling station (38), wherein said labeling station comprises a label printer (122) arranged to print a label comprising information specific to a patient for whom said pack is intended, and means for applying said label (138) to said pack; the system further comprising means for delivering (20/28) said pack from the labeling station so as to be accessible to a user, wherein the means for applying the label is

adapted to alter the way in which the label is applied depending upon the dimensions of the pack to be labeled (column 5, lines 2-17; column 9, lines 44-47).

31. Examiner notes the conveyor and palletizer stations (10/12/20/28/30) are treated as equivalent to the "means for selecting and retrieving" and the conveyor (20/28) is equivalent to "means for delivering" recited in independent claim 1 under 35 U.S.C. 112, sixth paragraph because the disclosed structure performs the identical function specified in the claim in substantially the same way, and produces substantially the same results as the corresponding element disclosed in the specification (i.e. robot 4). The labeler (138) is treated as equivalent to the "means for applying the label" recited in independent claim 1 under 35 U.S.C. 112, sixth paragraph because the disclosed structure performs the identical function specified in the claim in substantially the same way, and produces substantially the same results as the corresponding element disclosed in the specification (i.e. labeler, 22).

32. Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. Ex parte Thibault, 164 USPQ 666, 667 (Bd. App. 1969). Consequently, the pharmaceutical packs and labels are not structurally limiting to the currently claimed apparatus.

33. The examiner would like to note that while features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. In re Schreiber, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997); "[A]pparatus claims cover what a device is, not what a device does." Hewlett-Packard

Co. v. Bausch & Lomb Inc., 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (emphasis in original). A claim containing a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus" if the prior art apparatus teaches all the structural limitations of the claim. *Ex parte Masham*, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987). Examiner notes the phrases "comprising information specific to a patient for whom said pharmaceutical pack is intended" and "so as to be accessible to a user" are drawn to the intended use of the currently claimed apparatus and do not further structurally define the apparatus. See MPEP § 2114.

34. As to claim 74, Jenkins et al. discloses the apparatus is arranged such that the labeling station (38) applies the label in an orientation (column 5, lines 2-17; column 9, lines 44-47) relative to the pack. The phrase, "which is dependent upon at least one dimension of the pack" is drawn to the contents of the apparatus and does not structurally contribute to the currently claimed apparatus.

35. As to claim 75, Jenkins et al. discloses the labeling station is arranged to orient the pack and label applicator (138) appropriately (column 5, lines 2-17; column 9, lines 44-47).

36. As to claim 76, Jenkins et al. discloses the label applicator (138) is arranged to adjust its orientation (column 9, lines 44-47).

37. As to claim 77, Jenkins et al. discloses the labeling station is adapted to receive an instruction as to how the label is to be applied (column 9, lines 44-54).

38. As to claim 78, Jenkins et al. discloses the label applicator is arranged to apply the label at a predetermined position on the pack (column 5, lines 2-17; column 9, lines 44-47). The phrase "the position being variable from one pack type to another" is drawn to the contents of the apparatus and does not structurally contribute to the currently claimed apparatus.

39. As to claim 79, Jenkins et al. discloses the apparatus is arranged to pass information to the labeling station to enable the label applicator to apply the label in the predetermined position (column 9, lines 44-54).

40. As to claim 80, Jenkins et al. discloses the apparatus is arranged to pass label positioning information directly to the labeling station or label applicator (column 9, lines 44-54).

41. As to claim 81, Inclusion of material or article worked upon by a structure being claimed does not impart patentability to the claims. In re Young, 75 F.2d 966, 25 USPQ 69 (CCPA 1935) (as restated in In re Otto, 312 F.2d 937, 136 USPQ 458, 459 (CCPA 1963)). Therefore, the label size and pack size do not provide any structural limitations to the currently claimed apparatus. Jenkins et al. discloses the apparatus is arranged to apply a label of common size to all packs (See Figures 2 and 2A).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KIMBERLY K. MCCLELLAND whose telephone number

is (571)272-2372. The examiner can normally be reached on 8:00 a.m.-5 p.m. Mon-Thr.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Philip C. Tucker can be reached on (571)272-1095. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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